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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,755	10/30/2001	Toshihiro Shimizu	20039.0009USC1	1478

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
05/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/017,755	SHIMIZU ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7,9,11-19,21-24,29,31,50,51 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7,9,11-19,21-24,29,31,50,51 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 7, 9, 11-19, 21-24, 29, 31, 50, 51 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It appears that the present specification does not provide support for the limitation "first composition". The specification further does not appear to provide support for the limitations "fine granules comprise: (a) a first composition...(b) an enteric coating layer for the first composition". The present examples show that it is the fine granules that comprise the active agent and other excipients that are coated by an enteric coating composition, not the drug itself as recited in the claims.

Claim Rejections - 35 USC § 103

Claims 1-3, 7, 9, 11-19, 21-24, 29, 31, 50, 51 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg (US 6,132,770), in view of Watanabe et al. (Biol. Pharm. Bull. Vol. 18, No. 9) and Murthy et al. US 4,830,853.

Lundberg teaches an effervescent tablet comprising mixture of enteric-coated pellets (beads, particles, granules) containing lansoprazole as a proton pump inhibitor (ppi) in a core (acid-labile active substance) (column 3, lines 59 through column 4, lines 1-19). The core material is chosen from celluloses, sugar, non-pareils, or mixture thereof, having size of 0.1-4 mm (100-4000 μm) (column 8, lines 11-54). The ppi is mixed with filler, binder, lubricant, disintegrant, surfactant, other additives, and alkaline reacting agent (basic salt), including, calcium and magnesium salts (column 8, lines 55 through column 9, lines 1-5). The filler, binder, lubricant, disintegrant, surfactant, and other additives, including sodium lauryl sulfate, microcrystalline cellulose, mannitol, and hydroxypropyl cellulose are disclosed in column 22, lines 53-57). The pellets are coated with one or more enteric coating layers comprising methacrylic acid copolymers, and an over coating layer (column 10, lines 16 through column 11, lines 1-21). The coated pellets are compressed into tablets having hardness of 51-100 N (which if converted into kg would fall within the claimed range). Lundberg further teaches the tablet disintegrates in liquid at about 55 seconds (see examples).

Lundberg does not expressly teach the claimed amounts of the ingredients of claims 14-16. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Lundberg further does not expressly teach the oral disintegration time.

Watanabe teaches a rapid disintegrate compressed tablet comprising crystalline cellulose and low-substituted hydroxypropyl cellulose (L-HPC) (see page 1308, materials and methods section). The tablet which is rapidly disintegrated and dissolved in the mouth within 30 second, and having a crushing strength of 8-18 kg (see page 1308, and page 1309, results and discussion section). Thus, it would have been obvious for one of ordinary skill in the art to prepare the effervescent tablet of Lundberg using crystalline cellulose and L-HPC in view of the teaching of Watanabe to obtain the claimed invention, because the references teach the advantageous results in the use of similar disintegrating agents for the same purpose, such as, Lundberg teaches the effervescent tablet is especially suitable for patients with swallowing disorders and in pediatrics (column 3, lines 53-55), and Watanabe teaches that it is necessary to develop a new type of tablet having the characteristics of rapid disintegration and dissolution in saliva suitable for elderly patients, and patients having difficulties or experience inconvenience in swallowing (see page 1308).

Lundberg is further silent as to the teaching of using mannitol in the coating outside the enteric coating layer. However, Lundberg teaches an over coating layer outside of the enteric layer. The materials for the over coating include sugar (column 11, lines 1-5). Murthy teaches sugar includes mannitol (column 4, line 31). Thus, it would have been obvious to one of ordinary skill in the art to modify the over coating composition of Lundberg to include mannitol, because mannitol is well known in

pharmaceutical art as sugar or sugar alcohol, and because Lundberg teaches the use of sugar in the over coating layer.

Response to Arguments

Applicant's arguments filed 02/08/07 and 03/20/07 have been fully considered but they are not persuasive.

Applicant indicates in page 7 of the remarks dated 02/08/07 that a Declaration to be submitted to show tablet hardness is increased nearly 50% with coating containing mannitol 50% comparing to coating without mannitol. Upon reviewing the present examples, the examiner is unable to determine any unexpected result from the use of mannitol in the coating. See examples 3 and 9 which do not contain mannitol coating, the tablet hardness is 4.2 kg. While examples 4-8 which contain mannitol coating exhibit tablet hardness of 3.9 kg, 2.6 kg, 3.1 kg, 3.2 kg, and 3.7 kg. Accordingly, upon reconsideration, the 103(a) rejection is maintained.

Applicant argues that neither Lundberg nor Wantanabe suggests the presence of sugar alcohol coating on the granules. However, applicant's attention is called to column 10, last paragraph bridging column 11, Lundberg clearly teaches the presence of sugar in the over coating layer.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAN
PRIMARY EXAMINER

Art Unit 1615